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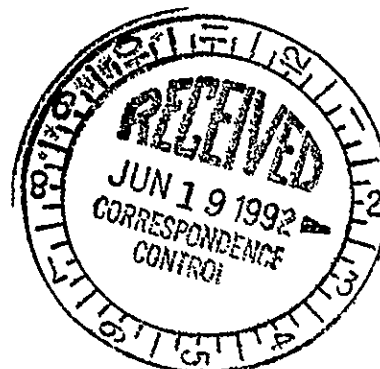
Department of Energy

9203665

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712 Swift Boulevard, Suite 5
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Mr. David B. Jansen, P.E..
Hanford Project Manager
State of Washington
Department of Ecology
Post Office Box 47600
Olympia, Washington 98504-7600



Dear Messrs. Day and Jansen:

RESPONSES TO REGULATORY COMMENTS ON REVISION 1 OF THE HANFORD SITE BASELINE RISK ASSESSMENT METHODOLOGY

This letter transmits responses to regulatory comments on Revision 1 of the "Hanford Site Baseline Risk Assessment Methodology" (HSBRAM), DOE/RL-91-45, to the U.S. Environmental Protection Agency, and State of Washington Department of Ecology to meet the 30 days allowed per Section 9.2.1 of the Hanford Federal Facility Agreement and Consent Order.

Comments on Revision 1 of the HSBRAM were dispositioned per the strategy for disposition of 100 Area Work Plan comments. Specifically, all comments were categorized as Accept, Discuss, or Reject and responses were provided to all parties prior to a meeting of the Risk Assessment Committee on June 9, 1992. At that meeting all comments were statused and plans to update the document were determined. Dispositions to all comments were agreed upon, with the exception of several comments where clarification is necessary. The Risk Assessment Committee will meet again on July 7, 1992, to finalize updates to the HSBRAM document so Revision 2 may be delivered as scheduled by August 15, 1992.

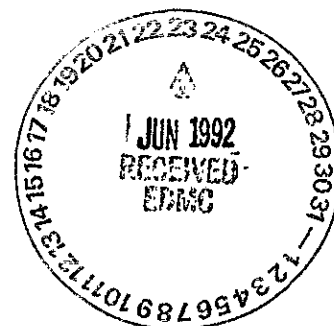
If you have any questions, please contact me at (509) 376-6798, Mr. K. M. Thompson at (509) 376-6421, or Mr. E. D. Goller at (509) 376-7326.

Sincerely,

Steven H. Wisness
Hanford Project Manager

Enclosure:
Comments On HSBRAM, Revision 1

cc w/o encl.:
R. E. Lerch, WHC
T. B. Veneziano, WHC



DISPOSITIONS TO COMMENTS ON THE HANFORD SITE BASELINE RISK ASSESSMENT
METHODOLOGY, DOE/RL-91-45, Revision 1, March 1992

Comments by the U.S. Environmental Protection Agency, D. R. Einan, EPA, to K. M. Thompson, RL, "Risk Assessment Methodology Document Comments," dated May 18, 1992.

Status Date: June 9, 1992

1. Section 2.1.3.1, page 9, second paragraph

The text discusses the use of background information that is currently being compiled to meet milestone M-28 and states that use of this background information should be evaluated case-by-case. The text should also state that if milestone M-28 data are not used for background, the rationale for using project-specific background data (for example aggregate area data or operable unit data) must be provided in the risk assessment.

Response: Accept. Additional Text as recommended will be added. Also see Ecology comment #12.

Status: Closed.

2. Section 2.2.5.4, page 32, second paragraph

The reference given for standard EPA equations and Health Effects Assessment Summary Tables (HEAST) methods, EPA 1992, appears to be incorrect. The reference cited for HEAST methods and calculations on page 39 of the methodology is "EPA 1989e." The correct reference should be cited.

Response: Accept. Correct reference will be cited.

Status: Closed.

3. Section 2.2.5.4, page 33, fifth paragraph

The text states that all photons with energies less than 400 keV are effectively shielded if the source is at least 1 meter deep. A reference should be given to support this statement. In some cases, a high activity source at a depth of 1 meter can contribute significantly to the total risk for the site if the source is not contained and there is a possibility of 1) transport via infiltration or 2) excavation under industrial or future land uses. The methodology should indicate that when buried sources are present, a shielding calculation will be performed to verify that the external pathway may be eliminated.

Response: Accept. A reference will be provided regarding shielding of low-energy photons. Text will be added to address excavation as a result of future land use, and use of shielding calculations to justify elimination of the external exposure pathway.

Status: Closed.

4. Section 2.2.5.4, page 34, third paragraph

The text should state that if radionuclide slope factors are not available from HEAST, the EPA Office of Radiation Programs will be asked to calculate the required slope factor.

Response: Reject. The 1992 version of HEAST (OHEA ECAO-CIN-821, March 1992) provides a complete list of slope factors for radionuclides. Requesting additional slope factors from the Office of Radiation Programs is no longer necessary.

Status: Closed.

5. Section 2.3.2, page 36, first paragraph

The text refers to subsection 2.3.2.1 twice in the second sentence. The text should be corrected to read "Subsections 2.3.2.1 and 2.3.2.2 discuss the toxicity values."

Response: Accept. The typographical error will be corrected.

Status: Closed.

6. Section 2.3.4, page 40, second paragraph

The next revision of the methodology should reflect new information regarding route-to-route extrapolation of toxicity values as provided in recently released EPA guidance (EPA 1991). In particular, oral toxicity values can be used to evaluate inhalation exposures.

Response: DISCUSS. Require clarification of source of EPA guidance regarding route-to-route extrapolation.

Status: Open. Clarifications to be discussed with the PRC representative for closure.

7. Section 2.4.1, page 42, second paragraph

The text states, "This linear equation . . . is an upperbound estimate based on the upper 95th percent confidence limit of the slope factor." This statement is incorrect. The equation is an upperbound estimate of the 95th percent confidence limit slope factor. The words "of the" should be deleted from the sentence.

Response: Reject. Text in question has already been corrected.

Status: Closed.

8. Section 2.4.1, page 43, third paragraph

9 2 1 2 6 3 9 1 2 3 5

The text discusses combining radionuclide and chemical cancer risks and states that risks contributed by radionuclides and chemicals should be summed. However, Section 10.7.3 in the Superfund risk assessment guidance (EPA 1989a) discusses when summation is and is not appropriate. Therefore, the second sentence in this paragraph should be deleted. The text should refer to Section 10.7.3 (EPA 1989a) for summation of radionuclides and chemical cancer risks.

Response: DISCUSS. Need to interpret and reconcile requirements of the NCP and guidance provided in 10.7.3 of RAGS. Points to consider:

- Section 10.7.3 of RAGS states (first paragraph that the cancer risk "resulting from radiological and chemical risk assessments may be summed in order to determine the overall potential human health hazard associated with a site."
- The possible "incompatibilities in the two estimates of risk" can be addressed as a source of uncertainty, but need not preclude the summation of these risks.
- There are certainly cases where summing risks from chemicals alone seems ludicrous (e.g., adding risks from Group A and Group C carcinogens). Likewise, adding internal and external radiation doses is fraught with uncertainty. However, both are routinely performed, and the "incompatibility" of the two numbers is considered a source of uncertainty.

Status: Closed. The quote from RAGS on page 43 of the HSBRAM will be removed. Section 10.7.3 of RAGS will be referenced. Change "must" to "may" in the 2nd sentence of the last paragraph of section 2.4.1 on page 43.

9. Section 3.1, page 49, first paragraph

The focus of the environmental evaluation should be on critical and sensitive habitats of protected species.

Response: Accept. The paragraph will be clarified to demonstrate the focus of the environmental evaluation.

Status: Closed. After discussion it was determined that "with a focus on" should be changed to "especially" with appropriate change to sentence structure.

10. Section 3.1, page 49, third paragraph

The following comment submitted as part of the October 30, 1991 technical review was accepted but is not adequately incorporated into the document:

This paragraph discusses the reduction of the range of potential stressors to "only the releases of site contaminants." However, part of the environmental evaluation process is to determine potential exposure pathways. Factors that may affect site

contaminant fate and transport, and therefore exposure pathways, include temperature, pH, salinity, water hardness, and soil composition (EPA 1989a). These factors should be included in the environmental evaluation.

The text should include a discussion the nonchemical factors noted above.

Response: Accept. The text will be edited to accommodate the non-chemical factors.

Status: Closed. Factors cited in the comment will be added to the text.

11. Section 3.1, page 50, first paragraph

It is recommended that the term "scoping" be included in the ecological evaluation process. Additional items to be considered under scoping include: estimates of potential or actual release of contaminants into the various environmental media, exposure pathways to potential receptors, general characteristics of receptors potentially exposed to contaminants, and possible or actual ecological effects of the contaminants or remedial actions (EPA 1989b).

Response: Acknowledge. The paragraph will be elucidated to explain the "scoping" and problem definition terms.

Status: Open. New text will be reviewed by EPA and Ecology for acceptance.

12. Section 3.1, page 50, third paragraph

The text discusses the use of indirect assessments and presents a freshwater example of such an assessment. However, indirect assessments in the terrestrial community may not be readily estimated quantitatively. Methods for qualitatively assessing the terrestrial community should be included. In addition, the freshwater example overlooks sediment contamination that is transferred into the food chain without ever being in the water phase.

Response: Accept in part. The text discusses the use of indirect assessments in the environmental evaluation and uses one readily available indirect assessment example. This example is the water quality criteria for the protection of freshwater aquatic life. No similar criteria for terrestrial organisms exists. The text will be modified to clarify this (e.g., limited freshwater sediment quality criteria are available).

Status: Closed. It will be stated that no similar criteria for terrestrial organisms or some aquatic organisms exists.

13. Section 3.1, pages 50, fifth paragraph

Species forming a major portion of the human food chain may also be a major portion of the food chain for predacious animals and scavengers (for example, peregrine falcon, American white pelican, and bald eagle). Therefore, species

should not be eliminated from the environmental evaluation based solely on their presence in the human food chain.

Response: Acknowledge. The authors agreed to the comment and the text has explained the same concept. See section 3.2.2.1 for identification of sensitive habitat and the selection of species in the environmental evaluation.

Status: Open. New text will be reviewed by EPA and Ecology for acceptance.

14. Section 3.2.1, page 54

Biota surveys are necessary to properly assess current site conditions, verify existing information, and identify chronic and acute stresses on the ecosystem. Biota surveys should be performed, or referenced if previously completed.

Response: Accept. The text will be revised to include biota surveys that may be conducted for a project-specific ecological investigation.

Status: Closed.

15. Section 3.2.2.2, pages 59 and 60

This section should address the indirect toxicity of contaminants that stress receptors and ecosystems (for example, altered pH, reduced dissolved oxygen, increased salinity, reduced decomposition rates, and nutrient cycling). Bioaccumulation potential should be addressed. Physical and chemical properties of contaminants such as water solubility and adsorption to soil particles should also be considered.

Response: Accept. The text will be modified to address the indirect toxicity of contaminants. Instead of modification in Section 3.2.2.2, the issues will be covered in other sections.

Status: Closed. Insert physicochemical parameters into appropriate sections in the text and cite locations to EPA and Ecology.

16. Section 3.2.2.2, page 60, second and third paragraphs

The text indicates that human health risk screening components are environmentally protective and applicable for the environmental evaluation. This may not be true in certain cases. There are numerous chemicals which are toxic or induce adverse behavior in organisms that do not cause cancer in humans. The environmental risk assessment should be evaluated by appropriate environmental methods as specified in EPA (1989c,d).

Response: DISCUSS. The reference cited (EPA 1989c) has been requested from the EPA contractor.

Status: Open for further discussion. Best professional judgement is required. EPA and Ecology considered the concept sound to expand and utilize the human screening process. Reference has been provided for review.

17. Section 3.2.2.2, page 60, fourth paragraph

It should be noted that some ecologically harmful chemicals do not have water or sediment criteria (just as some chemicals harmful to humans do not have MCL's and the like).

Response: Accept. A modification to the text will be added. It should be noted that many, or most, toxic chemicals have MCL and other criteria.

Status: Closed.

18. Section 3.2.2.3, page 61, first paragraph

The text states that assessment endpoints are analogous to receptor identification in the human health evaluation process. This statement is not always true and should be deleted.

Response: Accept. The statement will be deleted.

Status: Closed.

19. Section 3.3.2, page 66, third paragraph

The text discusses certain aspects of biological transport. Metabolism and life cycles should also be addressed under biological transport.

Response: Accept. The text will be modified to include metabolism and life cycles in the biological transport.

Status: Closed.

20. Section 3.4, pages 68, 73, and 74

Temporal and spatial components of risk characterization are not, but should be, addressed.

Response: Accept. Temporal and spatial components of risk characterization will be addressed in the text.

Status: Closed.

21. Section 3.4, page 68, fourth paragraph; page 73, first paragraph

The text presents a discussion on environmental hazard quotients. A reference should be provided for this discussion.

Response: Accept. The authors introduced the Environmental Hazard Quotient (EHQ) term. The text will be modified to indicate so with additional explanation.

Status: Closed. Provide additional explanation and reference; if possible.

22. Figure 3-4, page 69

The term "potential" in the title should be changed to "primary" because the figure illustrates the pathways of most significant exposure but does not address all potential exposure pathways.

Phytoplankton are assessed as the sole primary producer in the ecosystem. Macrophytes should also be included as primary producers.

Bio-uptake and ambient contact should be included as primary pathways for aquatic flora.

Respiration and ambient contact should be included as primary pathways for aquatic fauna.

The term "hyporheon" in the figure is not clearly represented. The hyporheon is the interstitial space between surface water and groundwater and is usually found in cobblestone or gravel streams. The type of migration from the hyporheon (chemical/physical, biotic, or both) should be identified and the corresponding pathways should be assessed.

Response: Accept in part. The first four comments are accepted and new text will be added to explain Figures 3-4 and 4-4. The fifth comment is rejected.

Status: Closed. Provide footnote with definition for "hyporheon."

23. Figure 3-5, page 70

The term "potential" in the title should be changed to "primary" because the figure illustrates the pathways of most significant exposure but does not address all potential exposure pathways.

The term "absorption" should be replaced with "bio-uptake".

Surface water should be addressed as a matrix of the riparian community.

Response: Accept in part. The term "potential" will be changed to "primary." The term "absorption" will be replaced with "sorption", and surface water will be added in the figure as a matrix to riparian and terrestrial communities.

Status: Closed.

24. Figure 3-6, page 71

The term "potential" in the title should be changed to "primary" because the figure illustrates the pathways of most significant exposure but does not address all potential exposure pathways.

The term "absorption" in the figure should be replaced by "bio-uptake".

Response: Accept in part. The term "potential" will be changed to "primary", and the term "absorption" will be changed to "sorption."

Status: Closed.

25. Section 4.2, page 79, second paragraph

The text suggests that acceptable exposure levels in a medium for an individual substance would be based on a hazard quotient of 0.3. While 0.3 may be applicable to industrial scenarios where three principle pathways exist (soil ingestion, water ingestion, and air inhalation), the text should clearly state that for other exposure scenarios, 0.3 may not be acceptable. The determination of a target hazard quotient is more appropriately addressed case-by-case.

Response: DISCUSS. The authors recommend reducing the scope of the discussion on the qualitative risk assessment. The authors agree that modification of the discussion on the use of a 0.3 hazard quotient (HQ) for application to other scenarios is required. The authors also agree that an HQ of 0.3 should be the initial target when evaluating the more-or-less equal three pathways (soil ingestion, water ingestion, and air inhalation). The HQ departure from 0.3 should be evaluated on a case-by-case basis.

Status: Closed. The risk assessment committee will meet at 9AM on July 7, 1992, in the EPA conference room to develop a qualitative risk assessment methodology.

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REFERENCES

- EPA 1989a. Risk Assessment Guidance for Superfund, Volume 1. Human Health Evaluation Manual, Part A. Interim Final. EPA/540/1-89/002. U.S. Environmental Protection Agency. December 1989.
- EPA 1989b. Risk Assessment Guidance for Superfund, Volume 2. Environmental Evaluation Manual. Interim Final. EPA 540/1-89/001. U.S. Environmental Protection Agency. March 1989.
- EPA 1989c. Technical Appendix: Exposure Analysis of Ecological Receptors. For inclusion in Superfund Exposure Assessment Manual. Office of Emergency and Remedial Response, U.S. Environmental Protection Agency. December 1989.
- EPA 1989d. - Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. EPA/600/3-89/013. Office of Research and Development. U.S. Environmental Protection Agency. March 1989.
- EPA 1991. Human Health Evaluation Manual, Part B: Development of Risk-based Preliminary Remediation Goals. Publication 9285.7-01B. U.S. Environmental Protection Agency. December 1991.

**RECOMMENDED FORMAT
ENVIRONMENTAL EVALUATION METHODOLOGY REPORT**

- 1. Introduction**
- 2. Scope of the Environmental Evaluation**
 - 2.1 Objectives**
 - 2.2 Site characterization**
 - 2.2.1 Physical setting**
 - 2.2.2 Nature and extent of contamination**
 - 2.2.3 Ecosystems**
 - 2.2.3.1 Regional**
 - 2.2.3.2 Site-specific**
 - 2.2.3.3 Food webs**
 - 2.2.4 Existing information on ecological effects**
 - 2.3 Problem definition**
 - 2.3.1 Contaminant identification and screening**
 - 2.3.2 Sources of nonchemical stress**
 - 2.3.3 Habitats of potential concern**
 - 2.3.4 Endpoints**
 - 2.3.4.1 Assessment**
 - 2.3.4.2 Measurement**
 - 2.3.5 Conceptual site model**
- 3. Exposure Assessment**
 - 3.1 Potential receptors**
 - 3.2 Potential pathways**
 - 3.3 Endpoint evaluation**
 - 3.3.1 Quantitative analysis**
 - 3.3.2 Qualitative analysis**
 - 3.4 Land use**
 - 3.5 Uncertainty analysis**
 - 3.6 Summary of exposure assessment**

4. Toxicity Assessment

4.1 Parameter-specific dose-response data

4.2 In-situ dose-response data

4.3 Field studies

4.4 Endpoint evaluation

4.4.1 Quantitative analysis

4.4.2 Qualitative analysis

4.5 Uncertainty analysis

4.6 Summary of toxicity assessment

5. Risk Characterization

5.1 Quantitative endpoint evaluation

5.2 Qualitative endpoint evaluation

5.3 Uncertainty analysis

5.4 Summary of risk characterization

5.4.1 Evidence of environmental impact

5.4.2 Evaluation of observed impact

5.4.3 Potential future impact

6. Summary of Environmental Evaluation

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DISPOSITIONS TO COMMENTS ON THE HANFORD SITE BASELINE RISK ASSESSMENT
METHODOLOGY, DOE/RL-91-45, Revision 1, March 1992

Comments by the Washington Department of Ecology, S. F. Cross, Ecology, to E. D. Goller, RL, "Hanford Site Baseline Risk Assessment Methodology, Revision 1," dated May 19, 1992.

Status Date: June 9, 1992

1. Preface, page i.

Deficiency: The preface states USDOE position on four areas. The positions are incompatible with a tri-party risk assessment methodology, the TPA, and current activities (such as the Future Site Use Working Group). They are incompatible with a document to which Ecology is a party. Brief responses are as follows:

- ▶ To not use the four scenarios must be justified on a case by case basis. USDOE may not reserve a right to pollute groundwaters of the State through a claim of use or ownership.
- ▶ The three parties do not need to wait for a ROD to accept MTCA as an ARAR.
- ▶ The point of compliance for groundwater is below the waste site. The operable unit boundaries are not appropriate as points of compliance for air contaminants. The cleanup should result in the dissolution of operable units. See WAC 173-340-700(6) and -720.
- ▶ Institutional control as part of a remedial alternative will only be allowed when specifically justified case by case. See NCP 300.430(a)(1)(iii).

Even if the preface is deleted from this document, USDOE advocacy of these positions foreshadows disagreements incompatible with USDOE's declared mission of remediating the Hanford site.

Recommendation: These issues must be resolved to the satisfaction of Ecology prior to the next draft of the *Methodology*.

Response: Acknowledged. The issues will be addressed prior to the next draft of the Hanford Site Baseline Risk Assessment Methodology (HSBRAM).

Status: Closed.

2. Section 1.3, bottom paragraph of page 2.

Deficiency: An important reference is not included.

Recommendation: Include *Guidance for Data Useability in Risk Assessment*, EPA/540/G-90/008, 1990.

Response: Accept. The text will be revised to include the reference as a source of information for conducting baseline risk assessments.

Status: Closed.

3. Section 1.5.2, first full paragraph of page 5, first sentence.

Deficiency: The text incorrectly states that the overall goal of the ecological evaluation is "to determine cleanup levels." That conclusion does not follow from the excerpt of the NCP section 300.430(d)(4). Developing remedial alternatives is not synonymous with determining cleanup levels. See also section 3.1.

Recommendation: Delete the last four words of the sentence.

Response: Accept. The last four words of the sentence will be deleted.

Status: Closed.

4. Section 1.5.2, page 5, second full paragraph of page, second sentence.

Deficiency: The text is presumptuous in stating that satisfying NCP requirements will necessarily meet the general requirements of RCRA and the state. This has not been demonstrated.

Recommendation: Change the word "will" to "may".

Response: Accept. The word "will" will be changed to "may".

Status: Closed.

5. Section 1.5.2, page 5, last paragraph, last sentence.

Deficiency: The term "ecology" is incorrectly applied to domestic animals in the context of the environmental evaluation of the risk assessment.

Recommendation: Point out that the ecological evaluation applies neither to humans nor domestic animals.

Response: Accept. The focus of ecological evaluation will be clarified to

note that it does not include domestic animals or humans.

Status: Closed.

6. Section 2.0, page 7.

Deficiency: The data evaluation element is incorrectly labeled as "identification of contaminants of potential concern." The text incorrectly states that RAGS (EPA/540/1-89/002) exhibit 9-1 is a suggested outline for a baseline risk assessment, when it is actually an outline for a baseline risk assessment report.

Recommendation: Use RAGS terminology and procedure in the *Methodology*. Delete the first sentence of the third paragraph.

Response: DISCUSS: See Ecology Comment #10.

Status: Open. The first part of section 2 will be revised to emphasize Hanford site specific nature of the four bullets. The titles of the four elements will remain the same. Section 2.1 will be revised to address the nine steps. The nine steps are conducted as part of the data evaluation process that occurs for a Remedial Investigation (RI) report and may be addressed in sections of the RI report other than the baseline risk assessment. The risk assessor, however, should be aware of the nine steps and how they have been conducted for the specific RI report and baseline risk assessment. The risk assessor should discuss the quality of data in the Uncertainty Section of the risk assessment. Reference and discussion of TICs will be added to the Methodology. The nine steps are to be covered in the compromise. Text is to be provided to EPA and Ecology for review.

7. Section 2.1.1, page 7.

Deficiency: The text inappropriately applies the Pareto principle in support of reducing the number of chemicals of potential concern. Wadsworth (1990) does not support the use of the principle in the CERCLA risk assessment context. No citation is provided to document the use of the Pareto principle by the EPA. Ecology is concerned at the Hanford site with more than the "dominant" risk drivers, as there may be "subordinate" risk drivers that are significant.

Recommendation: Do not use the Pareto principle to support the practice of reducing the number of contaminants of potential concern. This practice may be justified by reference to RAGS (EPA/540/1-89/002) and EPA Region 10 guidance. Both RAGS and MTCA require that "screening" be justified prior to use on either a operable unit specific or a Hanford site basis. Also remove the last two sentences of the first paragraph of section 2.1.4 on page 13 and the second paragraph of page 17, section 2.1.5.

Response: Reject. The discussion on the Pareto principle is appropriate and should be retained in the HSB RAM. This principle is recognized in the scientific community. The concept that a large proportion of site-attributable risks may be caused by only a few hazardous substances is an excellent example of the Pareto principle.

The text will be reviewed for possible modification to include the additional references as noted by Ecology to RAGS and EPA Region 10 in addition to the Pareto principle. Recommendations from the reviewers on such modification would be welcome.

Status: Open. Text is under review for modification or provision of additional references.

8. Section 2.1.1, second full paragraph of page 8, second sentence.

Deficiency: a) This quoted material is incomplete. b) The parenthetical added to the quoted material is inappropriate. c) There is no specific reference to the page or section of RAGS from which the quotation was excerpted. d) MTCACR, WAC 173-340-708, includes provisions for the selection of "indicator hazardous substances," which are not mentioned in the *Methodology*.

Recommendation: a) Add a quotation of the second paragraph in RAGS section 5.9. b) Remove the added parenthetical, "[releases from]", from the already quoted material. c) Add a specific page or section reference to the RAGS citation. d) The goal of the *Methodology* to satisfy MTCA as well as CERCLA requirements can only be met by providing for the specific requirements of WAC 173-340-708(2).

Response: DISCUSS: The authors consider the quoted material adequate and the parenthetical statement appropriate. Additional references can be added.

Status: Close. Refer the EPA Region 10 guidance as being appropriate with backup of RAGS section 5.9 (which is not to be followed). Delete the quote from RAGS section 5.9 and provide the references.

9. Section 2.1.1, page 8, last paragraph of section, last sentence.

Deficiency: Reevaluation of EPA guidance is not within the scope of this methodology.

Recommendation: Delete this sentence.

Response: Accept.

Status: Close.

10. Section 2.1.2, top paragraph on page 9, second from last sentence.

Deficiency: The text does not recognize the distinction between the data evaluation steps of a risk assessment and the distinct data processing steps that are part of an RI. The risk assessor should not assume that the data evaluation for risk assessment criteria has been completed in the RI/FS as is indicated by this paragraph.

The risk assessor should not assume that the risk assessment type of data evaluation has been completed in the RI/FS, as is stated in this paragraph.

RAGS (EPA/540/1-89/002) chapter 5 specifies nine data evaluation steps "that should be followed to organize the data into a form appropriate for a baseline risk assessment." RAGS emphasizes that "prior to conducting any of these steps, the EPA [or Ecology] remedial project manager (RPM) should be consulted to determine if certain steps should be modified, added, or deleted as a result of site-specific conditions." It is inappropriate for the Hanford methodology to categorically eliminate any of the nine steps without EPA and Ecology agreement that such steps are not appropriate to the Hanford-specific conditions. EPA and Ecology have made no such determination.

"The outcome of the data evaluation is (1) the identification of a set of chemicals that are likely to be site-related and (2) reported concentrations that are of acceptable quality for use in the qualitative risk assessment." It is inappropriate to treat the whole data evaluation component of risk assessment as the outcome of its nine steps.

Recommendation: The Hanford risk assessment methodology must expressly provide for each of the nine steps. Each step must be completed unless the Ecology and EPA RPMs agree that such steps are inappropriate. State that it is the responsibility of the risk assessor to confirm that all steps recommended in RAGS have been satisfied.

Response: DISCUSS: The authors recommend this item be discussed at the meeting scheduled for June 9, 1992, and will provide a listing of the nine steps as a basis for the discussion.

Status: Open. Refer to Ecology comment #6.

11. Section 2.1.3.1, page 9-11.

Deficiency: This section exemplifies the surfeit of rationalization that permeates the *Methodology*.

Recommendation: The paragraph should be shortened.

Response: DISCUSS: Only a few sentences of "rationalization" can be deleted

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without removing important explanations (e.g., we could remove part of the last paragraph on page 9, "If such an error..." through the end of the paragraph). In addition, Ecology comment #12 seeks to introduce text which is very similar to that already in section 2.1.3.1.

Status: Open. Text will be submitted for review by EPA and Ecology.

12. Section 2.1.3.1, page 9-11.

Deficiency: The text suggests use of "project-specific" background and disparages the use of site-wide background. This is counter to the goal of the M-28 background study. The standard to use is natural background, rather than local background. Contamination from other sites at Hanford can not be applied to increase background levels.

The proposed selection process for control data could result in underestimation of the risk. The *Methodology* allows for use of site-specific control or background data that are different from the background data currently being compiled under Tri-Party Agreement Milestone M-28. This process could result in the selection of "control" or background data from locations impacted by the Hanford facility. Control data are used to identify contaminants to be included in the risk characterization. Use of control data from an area impacted by the Hanford facility will result in lower risk estimates by eliminating contaminants of concern for that site.

Recommendations: Explain that site-wide background values will be used as soon as available and to the fullest extent applicable. Use the natural background standard rather than the local background standard.

Insert the following after the last sentence in the first paragraph:

"Background conditions are currently being compiled for the Hanford Site as a whole under Tri-Party Agreement Milestone M-28. These data should adequately describe widespread anthropogenic sources, and will serve as basis for control data."

Insert the following at the beginning of the second paragraph.

"There are two considerations that may be used to identify the need for project-specific control data:

- the potential presence of contaminants from a facility outside the Hanford facility which is upwind, upgradient, or upstream of the Hanford facility which may have impacted areas not included in data for Milestone M-28. The facilities currently or historically in the vicinity of the Hanford facility to be considered include:
... (include a list of such facilities and a figure showing

their locations).

- the potential presence of localized differences in soil characteristics that would result in the levels of naturally occurring inorganics elevated above the concentrations identified in Milestone M-28.

The risk assessment should include a clear rationale and justification for the selection of project-specific control data based on these two considerations."

Response: DISCUSS: The authors recommend this item be discussed at the meeting scheduled for June 9, 1991.

Status: Open. Text will be submitted for review by EPA and Ecology.

13. Section 2.1.3.2, page 11, first paragraph of section, sentence.

Deficiency: The explanation of confidence intervals and error would be clarified by stating the null hypothesis. The null hypothesis is that on-site contamination concentrations are not higher than background. A type I error would be a conclusion that a contaminant is present, when it is not.

Recommendation: State the null hypothesis.

Response: Accept. The null hypothesis will be added to the text.

Status: Closed.

14. Section 2.1.3.2, second full paragraph of page 12, second sentence.

Deficiency: The text presumes that funding and schedule constraints are such that the control data sets are not anticipated to be large enough to conduct a meaningful test for normality. The text also states that the control data sets will be insufficient to conduct a nonparametric or distribution-free tolerance interval evaluation. Ecology has not agreed to either assumption.

Recommendation: Delete this sentence.

Response: Accept in part. It is extremely unlikely that control data sets will be large enough to prove normality [at least 50 samples would be required - MTCACR (173-340-708(11)(d) requires a minimum of 10 or 20 samples, an insufficient number to prove normality]. Instead of deleting sentences in question, an additional sentence will be added: "However, if the control data sets are sufficiently large, the assumption of normality may be satisfied and should be tested."

Status: Closed. Delete discussion of funding and schedule constraints and provide reference to technical justifications.

15. Section 2.1.3.2, second from the bottom paragraph on page 12, first sentence.

Deficiency: The "censored data" terminology may be confusing to nonstatisticians. The common meaning of the word would be disturbing in this context.

Recommendation: Explain or define the term "censored data."

Response: Accept. The term "censored data" will be defined as appropriate.

Status: Closed.

16. Section 2.1.4.2, page 14, first paragraph of section, third sentence.

Deficiency: This is not an acceptable statement of the "foreseeable future." It is contrary to current efforts, such as the work of the Future Site Use Project Working Group. The issue was raised in the preface, and may best be resolved in that context.

Recommendation: Remove the second clause of this sentence.

Response: Accept. The second clause of the sentence in question will be removed.

Status: Closed.

17. Section 2.1.4.2, page 14, fifth full paragraph.

Deficiency: Guidance documents do not designate pathways as driving risks at sites. Although these pathways are considered basic to any risk assessment, they are not identified as risk drivers.

Any selection of pathways as risk-drivers must be accompanied by documentation. o However, recent research has shown that in addition to the standard pathways such as ingestion of water, there are pathways that can results in equal or greater exposure than the pathways called risk drivers in the *Methodology*. For example, inhalation of indoor air and dermal contact with tap water can result in exposures equal or greater to that from ingestion of water alone. The dose from inhalation of indoor air has been shown to 1.5 to 6.0 times as great as the dose from ingestion. Human Exposure to Volatile Organic Compounds in House hold Tap Water: The Indoor Inhalation Pathway, Thomas E. McKone, Environmental Science and Technology, 1987, Vol. 21, No. 12, pages 1194-1201. For dermal exposure, studies have predicted that the average adult during a 20 minute shower may be exposed to the same amount of chemical

as from ingestion of 1.4 liters of water a day (Dermal Uptake of Dilute Aqueous Trichloroethylene by Hairless Guinea Pigs, K.T. Bogen et al, AAMRL-TR-90-078, Environmental Sciences Division, Lawrence Livermore National Laboratory, University of California, Livermore, California, June 1990.

Recommendation: Delete this paragraph.

Response: Accept in part. Text will be revised to remove reference of the three pathways as being risk drivers. However, other rationale for their use (that they occur at most sites, are basic to any risk assessment, and development of default parameters are largely geared toward these pathways) will be retained to justify their use in calculating risk-based benchmark concentrations.

Section 2.2.1, page 18, fourth paragraph.

Recommendation: Include the following statements from the *Site Characterization Plan*: that "evapotranspiration levels can vary greatly with location at Hanford," that the evapotranspiration levels "were from five to nine times the mean annual precipitation," and that "during significant precipitation events, water can move below the vegetative root zone and escape evapotranspiration processes."

Status: Closed.

Comment: The uniqueness of the Hanford Reach is not correctly characterized. The Columbia River below Bonneville Dam is not impounded by a dam.

Status: Closed.

20. Section 2.2.1, second full paragraph of page 20, last sentence.

Deficiency: The text implies that ponds and ditches are only found in the 200 area.

Recommendation: Point out that there are also ditches and ponds in the 100 and 300 areas.

Response: Accept. The text will be added to indicate that there are ditches and ponds in the 100 and 300 areas.

Status: Closed.

21. Section 2.2.2, page 20, first paragraph of section.

Deficiency: a) The first sentence defeats much of the purpose of the *Methodology* by suggesting that populations be determined on a site-specific basis. b) This paragraph only discusses current populations. Current Hanford land use involves the use of pervasive institutional controls. Reliance on institutional controls in a risk assessment is contrary to NCP 300.430(a)(1) and RAGS (EPA/540/1-89/002).

Recommendation: a) The *Methodology* should characterize populations as broadly as possible, at the aggregate area level for instance. b) The characterization of potentially exposed populations must include future populations based on the four standard scenarios.

Response: Accept in part. Text will be added to make a distinction between current and future receptor populations, and that four standard scenarios will serve as the basis for characterizing possible future receptor populations.

Status: Open. Ecology continues to express concern about the text. EPA and RL consider the text adequate.

22. Section 2.2.3.2, page 25.

Deficiency: The lists of pathways are not complete. OSWER Directive 9285.6-03, section 6.0 includes two more routine pathways. The EPA Region 10 Supplemental RAGS, table III, also includes several more pathways, and does not distinguish primary and secondary pathways.

The *Methodology* makes an unsubstantiated distinction between pathways. The OSWER Directive makes no distinction between primary and secondary pathways.

The statement that secondary pathways should only be qualitatively evaluated, but may be qualitatively evaluated is unsubstantiated and unacceptable. The text neglects to mention that both quantitative and qualitative assessments of

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risk should be evaluated in an uncertainty analysis. However, no uncertainty estimate is possible in a qualitative assessment of risk, so the uncertainty analysis would be relatively meaningless. *Guidance for Data Useability in Risk Assessment*, EPA/540/G-90/008.

The bullets are not consistent with figure 2-4.

Recommendation: Include the all pathways relevant to Hanford site risk assessments. Substantiate or remove the primary/secondary pathway concept. Explain whether the bulleted items on page 25 are intended to be consistent with the EPA guidance or with figure 2-4.

Response: DISCUSS: The list of pathways is not inconsistent with OSWER Directive 9285.6-03 or EPA Region 10 Supplemental RAGS (Table I11). The sixth paragraph on page 25 clearly describes the biota pathways that have also been selected as primary exposure pathways. There is also no inconsistency between the text and Table 2-4. Discuss with Ecology the possibility of replacing "primary/secondary" terminology.

Status: Open. Comment will be reconsidered by S. F. Cross of Ecology.

23. Section 2.2.3.2, first sentence of first paragraph of page 26.

Deficiency: This sentence is incorrect in stating that there is a connection between contaminant-specific parameters and risk for a particular pathway. The risks for exposure pathways with contaminant-specific parameters can be equal to or greater than pathways without such parameters.

Recommendation: Remove this portion of the sentence.

Response: DISCUSS: Replace first sentence of paragraph with:

"Several pathways have been selected as secondary pathways because they represent exposure routes that depend on contaminant-specific factors, frequency or duration of exposures, or likelihood of occurrence. These secondary pathways may also contribute less to the overall risk or may require qualitative evaluation because of limited availability of contaminant-specific information."

Status: Open. Comment will be reconsidered by S. F. Cross of Ecology.

24. Section 2.2.3.2, second paragraph of page 26, last sentence.

Deficiency: The text states that most radionuclides have a small permeability constant, but does not specify the minority of radionuclides that do not.

Recommendation: Specify what is "low" for a permeability constant, and

explain how low is low. Specify which radionuclides do not have a "low" permeability constant.

Response: DISCUSS: The sentence in question is nearly a direct quote from RAGS (10.5.5). Discuss whether citing RAGS would be adequate, or if text should provide more detail.

Status: Closed. Text will be inserted regarding the radionuclides at Hanford, such as tritium, that may have high permeabilities.

25. Section 2.2.3.2, first sentence of second full paragraph of page 27.

Deficiency: The text states that the risk assessor may consider other pathways.

Recommendation: Point out the lead regulatory or USDOE unit manager may also require evaluation of other pathways.

Response: Accept. The text will be revised to include general reference to the risk assessor, lead regulatory unit manager or USDOE unit manager who may identify the need to evaluate additional pathways.

Status: Closed.

26. Section 2.2.4, page 27, et seq.

A. **Deficiency:** The bottom paragraph on page 27 indicates that application of the four scenarios would have to be justified on a site-by-site basis for each risk assessment. This defeats the purpose of the *Methodology* to provide uniform guidance for the Hanford site. At present, all four scenarios must be applied in all risk assessments. Over time, the parties will reach understandings about certain areas where some of the scenarios will not be applicable.

Recommendation: Revise the thrust of the paragraph to explain that it is assumed that all four scenarios will be applied in every risk assessment, unless site-specific conditions justify otherwise.

Response: DISCUSS: The scenarios for a baseline risk assessment should be determined on a site-specific basis as discussed in Section 6.2.2 of RAGS (EPA 1989) and WAC 173-340-708.

Status: Open. Provide text to say that a decision will be made by the Unit Managers or the issue will be elevated in the procedure for Tri-Party Agreement issues resolution.

B. **Deficiency:** The second full paragraph on page 28 calls for the creation

of a site-specific commercial/industrial scenario. This methodology should be establishing a generic scenario.

Recommendation: Explain that only in exceptional cases, on agreement of the operable unit managers, will a site-specific scenario be developed.

Response: Accept. The text will be modified to clarify that only in exceptional cases, and on agreement with unit managers, will site-specific scenarios be developed.

Status: Closed.

C. **Deficiency:** The third full paragraph of page 28 distinguishes the use of the four Hanford-wide scenarios as future scenarios from the use of site-specific current scenarios. The site-specific current use scenario would be, essentially, a fifth land use scenario. This current/future land use timeframe is introduced in the Preface to this draft of the *Methodology*.

Recommendation: Use just the four Hanford-wide future-use scenarios.

Response: DISCUSS: How to address current land use (which is slightly different than the future industrial scenario). Discuss whether this represents a "fifth" land use, or if it is simply the standard industrial scenario modified with site-specific information.

Status: Open. Refer to Ecology comment #21.

27. Section 2.2.5, page 29, first sentence of section.

Deficiency: The text states that "exposure is defined as . . ." without reference.

Recommendation: Reference where this definition is derived or delete "defined as."

Response: Accept. The words "define as" will be deleted.

Status: Closed.

28. Section 2.2.5.4, second from bottom paragraph of page 33.

Deficiency: This discussion of the shielding effect of soil does not consider that the soil may be disturbed. Disturbances of up to fifteen feet deep may be expected under the four land-use scenarios, and should be considered. Deeper disturbances and mixing may occur during remediation; for example, as in the macroengineering report. There may be instances where unacceptable risk will justify or require cleaning up deeper than fifteen feet.

Recommendation: Add a discussion that exposures to soils up to fifteen feet deep may occur under the four land-use scenarios if the soil is disturbed, and that remediation may affect deeper soils.

Response: Accept in part. Discussion will be added to address exposures to soils up to fifteen feet deep as a result of the four land-use scenarios. However, the effect of remediation shall not be considered as this is a baseline risk assessment methodology.

Status: Closed. Also see EPA comment #3.

29. Section 3.

Deficiencies: The Environmental Evaluation methodology will not identify all sources of environmental impact because the scope and focus are limited in the following areas:

- Identification of habitats of potential concern
- Identification of contaminants of potential concern
- Selection of assessment and measurement endpoints
- Toxicity assessment
- Risk characterization
- Critical aspects that are not clearly discussed

The focus of the proposed environmental evaluation methodology is too narrow.

Recommendations: As described in the following comments, the scope and focus of each of these sections needs to be expanded to incorporate the concepts for Environmental Evaluation endorsed in RAGS, Vol 2.

Response: Reject. The focus of the environmental evaluation is limited to the areas mentioned in the text in order to provide a systematic approach to conducting the environmental evaluation within the context of the NCP requirements for the baseline risk assessment.

Status: Closed. Defer to following comments.

30. Section 3.1, page 49, first paragraph of section.

Deficiency: The purpose of the environmental evaluation is incorrectly stated. See also section 1.5.2.

Recommendation: The appropriate concept is that "the results of the baseline risk assessment will help establish acceptable exposure levels for use in developing remedial alternatives." NCP 300.430(d)(4).

Response: Accept. The text will be modified to include the appropriate concept as indicated.

Status: Closed.

31. Section 3.1, page 49, third and fourth paragraphs of section.

Deficiency: There is no explanation of the purported advantages of departing from the Fava, et al., framework. Although Fava, et al., was a preliminary document, the *Framework* will soon be formally issued by EPA.

Recommendation: Departing from the *Framework* should be justified to the satisfaction of all three parties, in light of the impending release of the guidance.

Response: Reject. The Fava et.al. document is a summary report only and justification for departing from this document is unnecessary. The EPA document, entitled "Framework for Ecological Risk Assessment" (EPA 630/R-92/001) which has just been released and will be reviewed to see if it is applicable to the baseline risk assessment and the HSB RAM.

Status: Open. Readdress issue upon all parties reviewing the "Framework for Ecological Risk Assessment," EPA/630/R-92/001, February 1992.

32. Section 3.1, page 50, first full paragraph.

Deficiency: "Habitat of potential concern" and "biological species of potential concern" are restrictive concepts. This appears to be screening procedure that could improperly eliminate significant risk.

Recommendation: See section 3.2.2.1.

Response: Reject. The "habitat of potential concern" and "biological species of potential concern" are general discussion concepts. They are not meant to be screening procedures to eliminate significant risk.

Status: Open. Comment to be reviewed by S. F. Cross of Ecology.

33. Section 3.1, second full paragraph of page 50, last sentence.

Deficiency: It is not appropriate to state that the focus of ecological importance is usually not on individuals, but populations. Such a conclusion, if appropriate, properly belongs under the determination of endpoints.

Recommendation: Delete this sentence.

Response: Reject. The Ecological Assessment of Hazardous Waste Sites

(EPA/600/3-89/013) states that the principal ecological effects are on the population- and community-levels, not on individuals.

Status: Closed. Reference to section 2.4.1 of the document cited in the response will be added to the text.

34. Section 3.1, fourth full paragraph of page 52, sentence.

Comment: NPL site and aggregate area are not the same. List aggregate area as a separate item.

Response: Accept. Aggregate area will be separated from NPL sites and will be listed as a separate item.

Status: Closed.

35. Section 3.2.1, page 54, first paragraph of section, first sentence.

Deficiency: The level of ecological study at the Hanford site relative to most NPL sites is not documented.

Recommendation: Delete the first clause.

Response: Reject. There are documented ecological studies for the Hanford area. For example, a public document entitled "Fiscal 1991 - 100 Areas CERCLA Ecological Investigations," WHC-EP-0448, contains a wealth of ecological information for the area.

Status: Closed. Cite examples in text if possible.

36. Section 3.2.1, bottom paragraph of page 54, second and third sentence.

Deficiency: The U.S. Dept. of Interior has determined that significant natural resource concerns have the potential to be affected by releases from the sites at Hanford. A natural resource damage assessment conducted by any of the natural resource trustees would be based on injuries to natural resources remaining after cleanup. There is a critical need to involve the trustees in the ecological evaluation.

Recommendation: Revise the paragraph so that, instead of indicating that natural resource trustees will have little interest or involvement in Hanford cleanup, there are commitments to solicit trustee involvement in the ecological evaluations and cleanup decisions.

Response: Accept. The text will be revised to indicate that there are commitments to solicit natural resource trustee involvement in Hanford ecological evaluation and clean up decisions.

Status: Open. Text will be provided to EPA and Ecology for review.

37. Section 3.2.2.1, page 55.

Deficiency: This process is restrictive. There may be habitats that do not meet the ESA regulatory definition that will nonetheless be addressed in the environmental evaluation. There may be species outside of "critical habitats" that will be addressed in the ecological evaluation. This section does not recognize the use of biomarkers, which may be measured in "unimportant" species. Notwithstanding the above, the definitions of habitats of potential concern in the context of this *Methodology* should not be restricted to those used in the ESA regulations. The definition of habitat of potential concern would have to include any habitats identified in the conceptual model as potentially exposed to contaminants.

Recommendation: Do not use the concepts of habitat of potential concern and species of potential concern.

Response: Reject. The "habitat of potential concern" and "biological species of potential concern" are general concepts.

Status: Open. Comment is to be reviewed by S. F. Cross of Ecology.

38. Section 3.2.2.2, page 58-60.

Deficiency: The selection of contaminants of potential concern does not include consideration of those without ARARs that could accumulate in the food chain. The assumption that the human health methodology is also protective of the environmental is unsubstantiated, and has recently been brought into question. See *Superfund Report*, May 6, 1992, page 21.

Recommendation: Include provisions for identifying contaminants without ARARs for terrestrial and aquatic food chain effects. Remove statements linking human health and environmental evaluation.

Response: DISCUSS: In addition to the screening process discussed in the document, a recommendation and discussion for the use of "best professional judgement" to evaluate additional contaminants of potential concern can be added to this section.

Status: Open. See EPA comment #16.

39. Section 3.2.2.3, page 61, second paragraph.

Deficiency: The definition of measurement endpoint is inadequate. The definition of measurement endpoint from the top of page 42 of RAGS Vol. II (EPA/540/1-89/001) provides a sentence that clarifies the relation of

assessment to measurement endpoints.

Recommendation: Insert: "Measurement endpoints are those used in the field to approximate, represent, or lead to the assessment endpoint."

Response: Accept. The "measurement endpoints are those used in the field to approximate, represent, or lead to the assessment endpoint" will be inserted in the text.

Status: Closed.

40. Section 3.2.2.3, page 61-62.

Deficiency: Indicator species are the only example of measurement endpoints included.

Recommendation: Expand the examples of assessment and measurement endpoints to include those listed in tables 2-3 and 2-4 of *Ecological Assessment of Hazardous Waste Sites*, EPA/600/3-89/013.

Response: Accept. The examples of assessment and measurement endpoints will include those listed in tables 2-3 and 1-4 of *Ecological Assessment of Hazardous Waste Sites*, EPA/600/3-89/013.

Status: Closed.

41. Section 3.2.2.3, page 61, third paragraph.

Deficiency: It is not clear of what this paragraph is an example.

Recommendation: Specify the concept that this paragraph on indicator species exemplifies.

Response: DISCUSS: The authors request clarification on the concern expressed in the comment.

Status: Closed. An editorial review of the second and third paragraphs will be performed to clarify the concepts.

42. Section 3.2.2.3, second paragraph of page 62, second sentence.

Deficiency: The last part of this sentence is unrelated to the first part. Biology itself is not an exact science. The methodology will not address budget and schedule restraints.

Recommendation: Delete ", but the actual selection is far from an exact science, and most projects are highly constrained by schedule and budget".

Response: Accept in part. The paragraph will be clarified and revised to state:

"Endpoint selections are highly site-specific. Two EPA documents, "Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference" (EPA 1989h) and "Selection and Ranking of Endpoints for Ecological Risk Assessment" (EPA 1989d) provide useful guidance on the selection of appropriate endpoints. The actual selection, however, is far from an exact science. Table 3-3 provides some characteristics of good assessment and measurement endpoints."

Status: Closed.

43. Section 3.2.2.3, page 63, table 3-3.

Deficiency: Several of the items were changed from the EPA guidance with no explanation and resulting improvement in clarity or content. The list itself is vague without the EPA text.

Recommendation: Change "easily measured" back to "readily measured". Delete "cost-effectively measured". Explain that the items are explained in the EPA guidance, and provide a specific page or section reference.

Response: Accept in part. The specific reference will be cited and the word "easily" will be changed to "readily".

Status: Closed.

44. Section 3.3, page 64, second full paragraph.

Deficiency: The cause and effect relationship of the first sentence is not explained. It is not explained why reasonable maximum exposure concepts entail the use of mean values.

Recommendation: Provide explanations.

Response: Accept. The text will be revised to clarify the maximum exposure concepts and more specific cross-references to Chapter 2 will be added, as appropriate.

Status: Open. Text will be provided for review by EPA and Ecology.

45. Section 3.3.1, page 64, second paragraph of section, second sentence.

Deficiency: This paragraph could be improved, and the *Methodology* enhanced by providing more detailed guidance. The fact that there is less standardized ecotoxicological data than human health toxicological data creates a need for

the *Methodology* to address or develop site-specific information. Because there are a limited number of habitats covering extensive areas of the Hanford site, this should be manageable. It may require a follow-up effort to supplement this *Methodology*.

Recommendation: The *Methodology* should provide for the development of site-specific ecological information.

Response: DISCUSS: In the authors opinion, the methodology provides for the development of site-specific ecological information. Additional discussion on the subject is welcome.

Status: Open. Comment to be reviewed by S. F. Cross of Ecology.

46. Section 3.3.1 and 3.3.2, pages 64-67.

Deficiency: The text only discusses ecotoxicological data that is available in the scientific literature. Ecotoxicological data from in-situ test or field studies are not included. There are many instances when data on certain contaminants or types of exposure will not be available in the literature. If the impact of these chemicals is to be considered, then Hanford-specific toxicity tests will need to be conducted, and ecological data compiled from special studies.

Recommendation: Expand the discussions in both sections to include in-situ toxicological tests and ecological field studies.

Response: Accept. The discussion will be expanded to include in-situ toxicological tests and ecological field studies, as appropriate.

Status: Open. Text will be provided for review by EPA and Ecology.

47. Section 3.4, page 68, second paragraph of section.

Deficiency: What does "integrated by comparison" mean? How are the results extrapolated? How does one profile exceed another?

Recommendation: Answer these questions in the text.

Response: Accept. The sentence will be modified to clarify "integrated by comparison".

Status: Open. Text will be provided for review by EPA and Ecology.

48. Section 3.4, page 68, fourth and fifth paragraphs of section.

Deficiency: No reference is provided for the use of a procedure such as the environmental hazard quotient (EHQ) ratio, the exposure profile:dose-response ratio, and the environmental hazard index (EHI).

Recommendation: Provide a reference that justifies the use of such a procedure, and explains or demonstrates how it is conducted.

Response: Accept. The text will be revised to provide an explanation of EHQ.

Status: Closed. Refer to EPA comment #21.

49. Section 3.4, page 73, second full paragraph.

Deficiency: What is a "subjective probabilistic" evaluation.

Recommendation: Explain this concept.

Response: Accept. A reference or short explanation will be provided.

Status: Closed. Text will be provided for review by EPA and Ecology.

50. Section 3.4, page 74, last two paragraphs of section.

Deficiency: Several critical components of environmental evaluations are not included as section headings. No outline for the reports is included.

Recommendation: Use the attached outline and include a discussion of any headings currently missing from section 3.

Response: DISCUSS: The outline provided will be discussed.

Status: Open. The ecological evaluation is being reviewed in terms of the "Framework for Ecological Risk Assessment," EPA/630/R-92/001, February 1992. Use of the outline presented will be determined in terms of the framework and the deliverable required for the Remedial Investigation Phase 1 reports for CERCLA investigations.

51. Section 4.1, page 76-77, third paragraph of section.

Deficiency: Ecology commented on this paragraph in the prior draft. The five criteria are presented out of context, and are beyond the scope of this methodology.

Recommendation: Refer to Ecology comments 50 and 51 on the prior draft of the *Methodology*.

Response: Reject. The HSB RAM should be discussed within the context of the MTCACR. It identifies constraints under which the results of the risk assessment may be evaluated and helps put into perspective how the HSB RAM meets these constraints.

Status: Open. To be discussed internally by RL.

52. Section 4.1, first and third full paragraphs of page 77.

Deficiency: These paragraphs do not recognize that carcinogenic risks for individual substances may not exceed 10^{-6} under Method B, or 10^{-5} under Method C. The cleanup levels for individual substances may be adjusted downward in the case of multiple substances/pathways so long as the cumulative risk does not exceed 10^{-5} . Individual substances may not pose a risk greater than 10^{-6} under Method B.

Recommendation: Revise this paragraph to provide for individual substance cleanup levels. This comment also applies to section 4.2, page 78, last sentence.

Response: Accept. Text will be revised as recommended.

Status: Open. To be discussed internally by RL.

53. Section 4.2, page 78, first paragraph, second to last sentence.

Deficiency: It is not correct to state that the qualitative risk assessment includes "other site information." The qualitative risk assessment is one set of information which will be considered along with other site information in determining whether an IRM is appropriate.

Recommendation: State that the qualitative risk assessment provides the characterization of site risks that TPA representatives will evaluate with other site information to determine whether an IRM is appropriate.

Response: Accept. The sentence will be revised to state "Thus, the qualitative risk assessment will provide the characterization of site risks that TPA representative will evaluate with other site information to determine whether an IRM is appropriate."

Status: Closed.

54. Section 4.2, page 78, third paragraph.

Deficiency: This paragraph neglects to explain the role of ARARs.

Recommendation: Explain that the cleanup requirements of ARARs can also

justify an IRM.

Response: Accept. Add final sentence to third paragraph stating "In addition to a risk-based trigger, an IRM may also be initiated by an ARAR trigger as discussed in DOE-RL (1991)."

Status: Closed.

55. Section 4.2, page 78, fifth paragraph.

Deficiency: Even if the industrial/commercial scenario is used for screening purposes, it may not therefor be used for establishing acceptable exposure levels. The goal of IRMs is to achieve final cleanup levels, and avoid the expensive "second pass." The land use statements in this paragraph are unacceptable to Ecology. Use of the other scenarios will not screen fewer sites, because the qualitative risks of the sites may be ranked under any scenario.

Recommendation: A qualitative risk assessment in support of an IRM may not rely on the Hanford Site Development Plan, or scenarios based on institutional control of the site. The process of screening sites for conducting IRMs must not be confused with the determination of cleanup levels. It is feasible to use other scenarios for screening in a ranking framework rather than a threshold framework.

Response: DISCUSS: Recommend reducing the scope of the discussion on the qualitative risk assessment in this document.

Status: Closed. Defer to the Risk Assessment Methodology Committee meeting scheduled for July 7, 1992, at 9 AM in the EPA Hanford Office conference room.

56. Section 4.2, third paragraph on page 79.

Deficiency: IRM cleanup goals should be to meet final cleanup levels, and to avoid "second passes." Cleanup must remove all "unacceptable" risk, not just most risk.

Recommendation: Delete this paragraph.

Response: DISCUSS: Recommend reducing the scope of the discussion on the qualitative risk assessment in this document.

Status: Closed. Defer to the Risk Assessment Methodology Committee meeting scheduled for July 7, 1992, at 9 AM in the EPA Hanford Office conference room.

57. Appendix A, tables.

Deficiency: Different age groups are used to represent different pathways for the same media.

Recommendation: Explain that the numbers in the tables are default parameters available from the EPA and Ecology, and do not necessarily dictate pathway/age group relationships. The methodology should clearly state that both children and adult age groups should be used consistently for all pathways, unless documentation eliminates one.

Response: DISCUSS: The authors request clarification on the comment in order to address the concerns of Ecology.

Status: Open. Comment to be reviewed by S. F. Cross of Ecology.

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Subject: RESPONSES TO REGULATORY COMMENTS ON REVISION 1 OF THE HANFORD SITE
BASELINE RISK ASSESSMENT METHODOLOGY

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Approval	Date	Name	Location	w/att
		Correspondence Control	A3-01	X
		M. R. Adams	H4-55	
		L. D. Arnold	B2-35	
		G. D. Carpenter	B2-16	
		S. W. Clark	H4-55	
		R. E. Day	H4-55	
		C. K. DiSibio	B3-03	
		K. A. Gano	X0-21	
		A. D. Krug	H4-55	
		M. J. Lauterbach	H4-55	
		R. E. Lerch (Assignee)	B2-35	
		P. J. Mackey	B3-15	
		H. E. McGuire (Level 1)	B3-63	
		J. W. Roberts	H4-55	
		T. B. Veneziano	B2-35	
		T. M. Wintczak	L4-92	
		R. D. Wojtasek	L4-92	
		EDMC	H4-22	

Enclosures are the same as letter #9254519D, tmp. 6-5211.

*Reissue to cancel on 7/14/92 per Lauren Parchen.

